

Message

From: Strauss, Linda [Strauss.Linda@epa.gov]
Sent: 6/20/2017 4:43:15 PM
To: Beck, Nancy [Beck.Nancy@epa.gov]; Morris, Jeff [Morris.Jeff@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]
CC: Cleland-Hamnett, Wendy [Cleland-Hamnett.Wendy@epa.gov]
Subject: RE: Due ASAP FW: For final review -- GenX statement

Wonderful. OK to go?

From: Beck, Nancy
Sent: Tuesday, June 20, 2017 12:30 PM
To: Morris, Jeff <Morris.Jeff@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>
Cc: Strauss, Linda <Strauss.Linda@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Due ASAP FW: For final review -- GenX statement

I defer to Tala on accuracy, but it reads clearly to me.
Thanks.

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: 202-731-9910
beck.nancy@epa.gov

From: Morris, Jeff
Sent: Tuesday, June 20, 2017 12:18 PM
To: Henry, Tala <Henry.Tala@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Strauss, Linda <Strauss.Linda@epa.gov>
Subject: RE: Due ASAP FW: For final review -- GenX statement

So do my edits below make it more accurate? Thanks.

EPA is committed to protecting public health and supporting states and public water systems as the appropriate steps to address the presence of GenX in drinking water are determined.

EPA is initiating an investigation into Chemours's compliance with a 2009 order issued under the Toxic Substances Control Act (TSCA) for the production of GenX. This investigation will allow EPA to determine whether Chemours is in compliance with requirements of the order to control releases to the environment at the Fayetteville, N.C., facility. EPA is also reviewing the additional toxicity data submitted by the company, as required under the consent order, and updating the toxicity risk assessment using the more robust the additional toxicity database specific to GenX. At the request of the North Carolina Department of Environmental Quality (NCDEQ), EPA has agreed to perform independent laboratory analysis for GenX in some of the water samples being collected by NCDEQ at 13 locations in the Cape Fear River over the next three weeks.

Background

- Typically, EPA investigates potential TSCA noncompliance through a review of production and environmental controls records required by any rule or order and, as needed, an on-site inspection. EPA may also use information requests to inform our investigation.

- When EPA issued the consent order, the ~~toxicity~~ risk assessment for GenX was informed by ~~based on~~ the available toxicity data for GenX and analogous substances such as ~~for the analog~~ PFOA (also known as C8). The consent order required the company to conduct additional toxicity testing on GenX.
- EPA has received the data from Chemours and is using it to update its risk assessment.
- Chemours agreed to bear all costs for the water collection and testing. The samples are being sent to a private laboratory in Colorado, and the EPA Office of Research and Development laboratory in Research Triangle Park, NC for independent verification.

NCDEQ believes the completed results will be back from the laboratory in Colorado within four weeks from when the samples are received. EPA is working to determine a timeline for its analysis.

Under the Safe Drinking Water Act, EPA undertakes extensive evaluations of contaminants and uses the best available peer reviewed science to identify and regulate contaminants that present meaningful opportunities for health risk reduction.

~~While EPA has not established a drinking water regulation, health advisory or health-based benchmark for GenX in drinking water,~~ The agency is working closely with the states and public water systems to determine the appropriate next steps to ensure public health protection.

From: Henry, Tala

Sent: Tuesday, June 20, 2017 11:50 AM

To: Morris, Jeff <Morris.Jeff@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>

Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>

Subject: RE: Due ASAP FW: For final review -- GenX statement

So the highlighted language below presumes we have a toxicity assessment. Is this referring to the PMN review? Yes, we did a PMN risk assessment (aka Standard Review).

Is this really a toxicity assessment?

Both Hazard and Risk Assessment are part of a Standard Review risk assessment. We only considered workers though, as there were 'conditions' set forth to control releases to air and water.

Also this implies that in this review, analysis was based on what we know about PFOA—however aren't they structurally different?

The Standard Review risk assessment included hazard assessment for both GenX and PFOA; Structurally, there are differences, i.e., GenX is an ether whereas PFOA is straight acid; but there are also structural similarities (per fluoro acid). In our experience, GENERALLY, the pharmacokinetics and bioaccumulation of ethers vs. acids are different (ethers<<acids), but persistence in environment and toxicity are more similar. Other things come into play as well, such as chain length.

Would PFOA have been a good analogue?

Generally speaking in the world of PMNs, yes, PFOA would have been a decent analog; however, we also had the 28-day repeated-dose studies (rat and mouse) for GenX; which is what was ultimately used for POD & benchmark MOE for the assessment.

Hope this clarifies; it's a bit much to put into a sound bite. Let me know if have additional questions

Tala R. Henry, Ph.D.
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E: henry.tala@epa.gov

From: Morris, Jeff

Sent: Tuesday, June 20, 2017 10:45 AM

To: Beck, Nancy <Beck.Nancy@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>

Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>

Subject: RE: Due ASAP FW: For final review -- GenX statement

I had made comments this morning, which may not have made it to this version. I imagine it would have been the PMN assessment, and it would have been a risk assessment. We would have done the assessment on the best analog, since data were only subsequently generated and submitted per the consent order.

From: Beck, Nancy

Sent: Tuesday, June 20, 2017 10:03 AM

To: Strauss, Linda <Strauss.Linda@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>

Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>

Subject: RE: Due ASAP FW: For final review -- GenX statement

So the highlighted language below presumes we have a toxicity assessment. Is this referring to the PMN review? Is this really a toxicity assessment? Also this implies that in this review, analysis was based on what we know about PFOA—however aren't they structurally different? Would PFOA have been a good analogue?

One additional edit on the last sentence as well.

Thanks.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

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From: Strauss, Linda

Sent: Tuesday, June 20, 2017 9:59 AM

To: Beck, Nancy <Beck.Nancy@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>

Cc: Canavan, Sheila <Canavan.Sheila@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>

Subject: Due ASAP FW: For final review -- GenX statement

Nancy and Wendy, take a look at this version.

From: Grantham, Nancy

Sent: Tuesday, June 20, 2017 9:49 AM

To: Marraccini, Davina <Marraccini.Davina@epa.gov>; Harris-Young, Dawn <Harris-Young.Dawn@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Drinkard, Andrea <Drinkard.Andrea@epa.gov>; Maguire, Megan <Maguire.Megan@epa.gov>; Senn, John <Senn.John@epa.gov>

Cc: Jones, Enesta <Jones.Enesta@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>

Subject: For final review -- GenX statement

All – per our call just a few minutes ago, here is the final holding statement. Please make sure that your principals review asap – including Nancy Beck, Patrick Traylor, Sarah Greenwalt, and Richard Yamada.

Thanks all

ng

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Nancy Grantham
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